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ABSTRACT

As psychology has recognized the rights of clients and subjects to exercise a rational, voluntary choice about participation in research, assessment, and treatment, the use of written informed consent forms has increased. A sample of 196 psychologists in private practice were mailed questionnaires which examined their use of, and rationale for, written consent forms; the information covered by such forms; and the readability of the forms. Subjects returned completed questionnaires and copies of their consent forms which were then scored for readability. Of the 104 respondents, 30 reported using written consent forms. Users of written forms were significantly younger than non-users; there were no differences in frequency of use due to sex or theoretical orientation. The major reason cited for not using forms was a preference for verbal agreements. The content of the forms dealt primarily with issues regarding fees, and not with information which satisfies the requirements of informed consent, such as risks of treatment and alternative treatments. The average readability for the returned consent forms was "difficult," equivalent to an academically-oriented magazine. The findings suggest that therapists need to evaluate their practices regarding informed consent in order to increase clients' autonomy and their understanding of information provided. (NRB)

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Use, Readability, and Content of Written Informed Consent for Treatment

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Running Head: READABILITY OF INFORMED CONSENT FOR TREATMENT

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Abstract

Questionnaires were sent to 196 psychologists in private practice. Of the 104 (53%) respondents, 28.8% indicated that they used written consent forms. The major reason cited for not using them was a preference for verbal agreements. The content of the forms dealt primarily with issues regarding fees, and not with information which satisfies the requirements of informed consent, such as risks of treatment and alternative treatments. The average readability for the consent forms returned was "difficult," equivalent to an academically oriented magazine. It is concluded that therapists need to evaluate their practices regarding informed consent, in order to increase clients' autonomy, and their understanding of information provided.

Introduction

In the last thirty years, medical practitioners and researchers--as well as the legislators who regulate them--have paid increasing attention to the ethical and legal doctrine of informed consent (Annas, 1983; Lidz, et al., 1984). Psychology has also recognized the rights of clients and subjects to exercise a rational, voluntary choice about participation in research, assessment, and treatment. The American Psychological Association (APA) has stated that "psychologists fully inform consumers as to the purpose and nature of an evaluative, treatment, educational, or training procedure, and they freely acknowledge that clients, students, or participants in research have freedom of choice with regard to participation" (APA, 1981, p. 636). The present survey addressed three major aspects of written informed consent: a) the use of, and rationale for, written consent forms; b) the information covered by such forms; and c) the readability of the forms.

The major rationale for informed consent includes the ethical principles of autonomy and nonmaleficence (Beauchamp & Childress, 1983). Informed consent also encourages self-scrutiny by professionals. Free choice can only be made on the basis of adequate information. Such choice increases the responsibility of clients, and reduces the likelihood of exploitation. A somewhat more cynical view has been taken by Hare-Mustin, Maracek, Kaplan, and

Liss-Levinson (1979), who maintain that protection of therapists against malpractice suits, and against outside regulation of their profession, has been the major motivating force behind informed consent procedures.

Regardless of the rationale, psychologists have been paying more attention to providing written information to clients. Those arguing for a consumer orientation to therapy and the protection of the rights of clients have advocated the use of contracts (Adams & Orgel, 1975; Hare-Mustin, et al., 1978). Kovacs (1984), in urging independent practitioners to be more aware of informed consent for protection against malpractice suits, has advocated the use of a "brochure" as a means of providing such information. In addition to providing a record of the information covered, such forms may increase the autonomy of clients by making them somewhat less dependent on the therapist for information. In this regard, Morrow, Gootnick, and Schmale (1978) found that allowing cancer patients to take consent forms home significantly increased their recall of important information. This recall, along with a written form, increases clents' access to information which they can use to make choices regarding treatment.

The first purpose of the present survey was to assess the use of written informed consent forms by psychologists in private practice, and the reasons these psychologists have for their policies in this area.

The second issue concerns content of consent forms. Physicians are legally bound to provide patients with a description of the treatment, alternative treatment approaches, risks involved, anticipated problems, "any additional information other physicians would disclose in similar circumstances" (Annas, 1983, p. 254), and information that a reasonable patient in similar circumstances would need (Canterbury v. Spence, 1972). Kovacs (1984) has suggested private practitioners include 14 specific points, including

information regarding record-keeping, scheduling, fees, insurance coverage, limits of confidentiality, and grievance procedures "if required by your state" (p. 13). Notably absent in his list is information regarding nature of treatment, risks involved, and alternative treatments. This absence may be due to the purpose of his article, which was specifically addressing malpractice. Hare-Mustin, et al. (1979) argue strongly that such information be included in any informed consent procedure.

The second purpose of this study, then, was to assess the types of information that most often appeared on written consent forms.

In addition to the disclosure of information, understanding is a major component of informed consent (Meisel, Roth, & Lidz, 1977). A major danger in the use of written consent forms is that time may not be taken to insure that clients understand the information contained on the form (Vaccarino, 1978). Such a guarantee is stated in the Ethical Principles of Psychologists: "Psychologists respect the right of clients to have full explanation of the nature and purpose of the techniques in language the clients can understand [emphasis added]" (APA, 1981, p. 637). One way to measure the potential for such understanding is assessing the readability of the form itself. Readable forms do not insure understanding, but at least provide the potential for such understanding.

The empirical literature on readability of consent forms is not encouraging. Grundner (1980) analyzed five representative surgical consent forms using two common tests of readability. He found that one was written at the level of a specialized academic magazine, and the other four were as difficult to read as a scientific journal. Morrow (1980) applied a readability test to sixty cancer treatment consent forms, and found that the average readability was at the "difficult" level, that of an academically oriented

magazine. "The informed consent forms seemed to be slightly less difficult to read and understand than medical journals but substantially more difficult than materials from the popular press" (Morrow, 1980, p. 57). While these studies deal with medical procedures, there are data to suggest that the situation is similar in psychological research. Stuart (1978) found that providing informed consent forms to research participants did not guarantee their understanding of the experiment. In a study of institutional review boards (IRBs), the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978) surveyed consent forms used by 61 institutions, including universities as well as medical schools.

> No more than 15% of the consent forms were in language as simple as is found, for example, in Time magazine. In more than three fourths of the consent forms, fewer than ten percent of the technical or medical terms were explained in lay language. It is questionable whether subjects would find most consent forms very useful to them in making decisions regarding participation in research. (p. 56189)

Since verbal interaction is a primary tool of the psychologist in practice, we would like to believe that they would be more sensitive to such issues than physicians and researchers. Therefore, the third purpose of the present survey was to test the readability of written consent forms used by private practitioners.

Method

Questionnaires were sent to the 196 members of a state psychological association who were licensed, and who listed themselves as private practitioners. The first part of the questionnaire asked for demographic and professional data: age, sex, APA membership, year of degree and licensure, major theoretical orientation, and percentage of time spent in private practice. Respondents were then asked if they used written informed consent statements or contracts in their practice. If so, they were asked to submit those forms. They were then asked the following question: "We are interested

in the choices people make regarding the use of consent forms for psychological services. We would like to have your comments regarding your practices in this area."

The consent forms that were returned were scored for readability using two common tests, the Flesch Formula and the Fry Scale. Both tests use formulas based on the number of syllables per word and number of words per sentence of three 100-word samples from the text. The Flesch Formula (Flesch, 1948; Grundner, 1978) yields raw scores which usually range from 0-100, with 100 being the easiest (in some cases, a negative score is possible). Table 1 lists the Flesch raw scores, their corresponding levels of difficulty, and examples of representative reading materials. The Fry Scale (Fry, 1968, 1977) yields scores corresponding to grade levels from 1 to 17+ ("professional," beyond college level).

Insert Table 1 about here

Results and Discussion

Of the 196 questionnaires sent, 104 (53.06%) were returned. There were responses from 61 females and 43 males. The mean age of the respondents was 43.7 years. Ninety-one respondents had PhDs, eight had EdDs, and five had PsyDs. Ninety-three reported being members of APA, eleven had ABPP diplomas. In regard to major theoretical orientation, 50 reported being psychoanalytic or psychodynamic, 32 behavioral or cognitive, 13 eclectic, five humanistic, three family, and one did not answer that question.

Use of Consent Forms

Of the 104 respondents, 30 (28.8%) reported using written consent forms. Users of written forms were significantly younger (M = 39.70 years) than

nonusers (M = 45.38 years), $t(102) = -3.39$, $p < .002$. This may indicate a trend toward a greater use of written forms, or more exposure to such forms during training. There were no differences in frequency of use due to sex or theoretical orientation.

Rationale. The reasons practitioners give for using or not using written consent forms may provide some insight into their thinking about this issue. Thirteen people who use written consent forms responded to this question. The single most frequently reported reason for their use was the facilitation of fee collection; four respondents reported this reason. Three respondents mentioned ethical issues and responsibility in general. One other listed client protection; another, confidentiality. One respondent reported being "a strong believer in the use of such forms. I adopt a consumer oriented approach to psychotherapy, meaning a client has and should exercise more power than traditionally advanced. My policy statement is used at the end of each first session, and as I go over each point verbally, I ask my clients to think it over before signing." In this instance, the consent form seems not to be a substitute for, but a facilitator of, the conversation and relationship that constitutes informed consent (Kovacs, 1984, Vaccarino, 1978).

Eighteen people who do not use consent forms gave reasons for this policy. Of these, thirteen said they prefer verbal procedures. Five mentioned the forms getting in the way of the therapeutic relationship. Three more specifically mentioned that the forms were countertherapeutic. The argument that consent forms hinder the relationship reminds us of the classic argument teenagers use against birth control devices: i.e., that they spoil the "spontaneity" of the moment. We would argue, to teenagers and therapists, that such encumbrances can be defined as part of the relationship, in the same way that kissing is for teenagers, and setting fees is for therapists. Ulti-

mately, of course, the therapeutic impact of written forms--as well as orally presented information about risks and alternatives--is an empirical question.

One respondent had a unique (in our sample) view of responsibility: "Verbal contracts are preferable because they require the client to take complete responsibility even for remembering the terms of the contract." Clients should indeed be given reponsibility for their treatment, but entailed in this responsibility is the necessity for the client to have a significant proportion of power. If knowledge is power, and steps are not taken to assist clients' retention of that knowledge, then clients' power may be diminished. Such knowledge may not be an appropriate tool for transference or therapeutic ends, but may need to be considered part of the working alliance, which is just as important to safeguard (Weiner, 1975).

Another reason cited for not using consent forms is implied consent: "I accept the patient's presence as consent to treatment." This argument is suspect on three grounds. First, implied consent in medicine is only acceptable for procedures which are standard and routine, such as a checkup. Psychotherapeutic procedures do not fit that category, especially since practitioners vary so widely in their approaches and interventions. Second, implied consent assumes that clients already have knowledge and understanding of those procedures. "It cannot be assumed that those who seek therapy do so with adequate knowledge of therapy or its alternatives" (Hare-Mustin, et al., 1979, p. 5). Third, implied consent still does not reduce the potential for exploitation of the power differential in therapy relationships.

Nine respondents mentioned considering changing their policies: "I've considered a formal contract or consent form but have not yet used one because I have not decided what to include." "Haven't gotten organized to create one." These responses seem to indicate a lack of sensitivity to the ethical

issues involved, or at least some lethargy in dealing with them.

We are not necessarily arguing for use of written consent forms; rather, we are arguing for increased sensitivity to the issues involved. Given the use of written forms, the issues of content and readability become critical.

Content

The content most often represented on the nineteen consent forms in our sample dealt with financial issues. Seventeen forms covered method of payment, sixteen covered policies concerning fees for missed appointments. The next most common item--covered by twelve forms--was confidentiality and its limits. Of these, five mentioned potential danger, four mentioned suicidal potential, four mentioned child abuse, and three mentioned filing insurance. None of the forms covered all the limits.

Of these 19 forms, six mentioned the nature of treatment, five mentioned the purpose of treatment (four forms mentioned both), three stated benefits to be expected, and two mentioned alternative treatments. Among the forms, there was one mention each of possible risks, probability of success, and procedure for filing a grievance. None of the forms mentioned benefits or risks expected of alternative treatments, or prognosis without treatment.

The implication here is that if written consent is the only method used to convey information about treatment, we may indeed be helping to guard against malpractice suits, but not satisfying the ethical requirements of informed consent.

Readability

Of the 30 therapists reporting use of consent forms, 19 actually sent in their forms. Three of those were too short to be tested, so the Flesch and Fry tests were performed on 16 forms.

The mean Flesch readability score was 41.79, the median was 45.82. This

is in the "difficult" range, equivalent to an academically oriented magazine (see Table 1). The mean and median grade level from the Fry test was 12.5. The lowest score was at the 7th grade level, while three forms literally went off the Fry scale, and were scored 17+.

Since 13 of the 16 forms were from either behavioral or dynamic orientations, a t-test was performed on their Flesch readability scores. This test yielded a trend for the behavioral forms (M = 23.53 - "very difficult") to be less readable than the psychodynamic forms (M = 48.93 - "difficult"), $t(11) = 2.01$, $p < .07$. There were no differences in readability due to sex or age.

Interpretation of differences due to orientation is difficult because of the small sample, and because one behavioral form yielded an extreme readability score. The general readability results, however, seem to represent a state of affairs similar to that in medicine. These data give us no reason to suspect that psychologists are more sensitive to readability than are physicians.

It could be argued that individual clinicians are not sensitive, but groups and agencies, where several people collaborate on the production of forms, may be more so. Several lines of evidence, however, do not support the contention that agencies or committees yield forms with better readability. In their study of IRBs, the National Committee for the Protection of Human Subjects (1978) found the following:

> No significant difference was found on the average readability or completeness scores between consent forms as submitted to the IRBs and the consent forms as approved by the IRBs. This was true even on consent forms changed by the IRBs [emphasis added]. (National Commission, 1978, p. 56189)

For further evidence, we performed readability tests on several other forms. The model contract published by Hare-Mustin, et al. (1979), which is based on one designed by Ralph Nader's Health Research Group (Adams & Orgel,

1975), had a Flesch readability score of 42.43 (difficult). A model brochure published by the Division of Psychotherapy of APA (1983) had a readability score of 8.88 (very difficult). Finally, we solicited consent forms from one private and five public mental health facilities. The mean readability of these forms was 36.224 (difficult). A t-test showed that this was not significantly different from the scores of the private practitioners in our survey.

It is important to note that we do not know what conversations take place when these consent forms are discussed with clients. It is possible that clients' confusion is indeed dealt with, and understanding is good. Therefore, we cannot conclude that these clients' rights are being violated. All we can say is that they are not being protected on the basis of the written form alone.

It could be argued that when consent forms contain all the information they are supposed to, some of which is technical and by nature multisyllabic, they necessarily will be less readable. Indirect evidence against this is provided by the National Commission for the Protection of Human Subjects, who found no relationship "between the completeness and readability of consent forms. There was no tendency for the more complete consent forms to be either more or less difficult to read than were the less complete consent forms" (1978, p. 56189). Since the length of sentences seems to have a greater impact on readability scores than syllables per word, keeping sentences short can significantly increase readability.

It could also be argued that the average psychotherapy client may be more intelligent than the general population, and can read at a college level. This argument, however, implicitly discriminates against those with impoverished backgrounds, who may be the people whose rights it is most important to protect (Hare-Mustin, et al., 1979). Again, clients' understanding of these

consent forms is an empirical question. Until we know more, however, we suggest underestimating, rather than overestimating, the reading ability of clients, in order to assure that a greater percentage of clients understand the forms. Morrow (1980) suggess writing forms at a seventh to eighth grade reading level. He also recommends having patients, rather than peers, critique them. In light of the above evidence, we concur.

People who do not use consent forms are not necessarily derelict in their duty. However, it is clear that people who do use consent forms are not doing all they need to do. Therapists need to evaluate their practices regarding informed consent in terms of ethical principles such as autonomy, the ability of their clients to understand the forms used, and the range of information clients need to know in order to be properly informed. Such issues should be part of training for all therapists, as a way to guarantee that client rights will be as salient as therapeutic technique and professional practices (Handelsman, 1985; Hare-Mustin, et al., 1979; Tymchuk, et al., 1979).

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Table 1

Raw Scores, Difficulty Levels, and Representative Reading Materials for the Flesch (1948) Readability Test

Raw Score	Difficulty Level	Representative Reading
< 30	Very Difficult	Scientific Journal
30-50	Difficult	General Academically Oriented Magazine
50-60	Fairly Difficult	Quality Magazine
60-70	Standard	Digests
70-80	Fairly Easy	Science Fiction
80-90	Easy	Pulp Fiction
90-100	Very Easy	Comic Books